

## REMARKS

### **1. Formal Matters**

#### **a. Status of the Claims**

Claims 1-20 are pending in this application. Claims 1-20 are hereby cancelled without prejudice to pursuing these claims in a continuing application. Claims 21-40 are new. Upon entry of these amendments, claims 21-40 are pending and under active consideration. Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present application.

#### **b. Amendments to the Claims**

New claim 21 recites a nucleic acid consisting of 18 to 120 nucleotides, support for which may be found throughout the application including at claim 1, and paragraphs 18 and 30619 of the application as originally filed. New claim 21 also recites that the sequence of the nucleic acid may comprise (a) at least 18 consecutive nucleotides of SEQ ID NO: 2194, support for which may be found at Table 1, lines 15221-15225 and paragraph 30618 as originally filed.

Claim 21 is also amended to recite that the nucleic acid may be: (b) an RNA equivalent of (a), support for which may be found in the application as originally filed including at paragraph 18 of the application as originally filed.

Claim 21 is also amended to recite that the nucleic acid may be: (c) a sequence at least 56/69 identical to (a) or (b), support for which may be found at Table 1, lines 15221-15225 and paragraph 30619 of the application as originally filed. The nucleic acid represented by SEQ ID NO: 2194 forms a hairpin, as shown at Table 1, lines 15221-15225 and paragraph 30619 of the application as originally filed. The sequence of SEQ ID NO: 2194 is 69 nucleotides in length. Within the predicted hairpin formed by the nucleic acid of SEQ ID NO: 2194, 56 complementary nucleotides are paired.

Claim 21 is also amended to recite that the nucleic acid may be: (d) the complement of any one of (a)-(c), support for which may be found at paragraphs 18 and 30619 of the application as originally filed.

New claim 22 recites the nucleic acid of claim 21, wherein the at least 18 nucleotides comprises the sequence of SEQ ID NO: 5264, support for which can be found at Table 1, lines 15221-15225 and paragraph 30620 of the application as originally filed.

New claim 23 recites a nucleic acid of claim 21, wherein the nucleic acid consists of 18 to 24 nucleotides, support for which can be found at paragraph 18 of the application as originally filed.

New claim 24 recites a nucleic acid with a sequence consisting of (a) SEQ ID NO: 2194 (b) an RNA equivalent of (a); (c) a sequence at least 56/69 identical to (a) or (b); or (d) the complement of any one of (a)-(c), support for which may be found at new claim 21.

New claim 25 recites a nucleic acid of claim 21, wherein the at least 18 nucleotides is of a sequence selected from the group consisting of SEQ ID NO: 5264, support for which can be found at new claim 22.

New claim 26 recites a nucleic acid of claim 24, wherein the nucleic acid consists of 18 to 24 nucleotides, support for which can be found at new claim 23.

New claim 27 recites a nucleic acid of claim 22, wherein the nucleic acid is an RNA, support for which can be found at paragraph 18 of the application as originally filed.

New claim 28 recites a nucleic acid of claim 25 wherein the nucleic acid is an RNA, support for which can be found at paragraph 18 of the application as originally filed.

New claim 29 recites a nucleic acid of claim 27, wherein the nucleic acid is capable of modulating expression of a target gene, support for which can be found at paragraph 19 of the application as originally filed.

New claim 30 recites a nucleic acid of claim 28, wherein the nucleic acid is capable of modulating expression of a target gene, support for which can be found at paragraph 19 of the application as originally filed.

New claim 31 recites a nucleic acid of claim 29, wherein the nucleic acid is at least 14/21 complementary to a binding site sequence of 18 to 24 nucleotides of a target gene and wherein the binding site sequence is located in an untranslated region of RNA encoded by the target gene. Table 2, lines 151383-151482 show that among all listed target binding sites of the nucleotide represented by SEQ ID NO: 5264, the sequence of which is included in the sequence of SEQ ID NO: 2194, at the lowest level of complementarity a target binding site of 21 nucleotides has 14 nucleotides complementary to the sequence of SEQ ID NO: 5264; and (b) that the binding site sequence is located in an untranslated region of RNA encoded by the target gene, support for which can be found at paragraphs 21 and 30622 of the application as originally filed.

New claim 32 recites a nucleic acid of claim 30, wherein the nucleic acid is at least 14/21 complementary to a binding site sequence of 18 to 24 nucleotides of a target gene and wherein the binding site sequence is located in an untranslated region of RNA encoded by the target gene, support for which can be found at new claim 31.

New claim 33 recites a vector comprising an insert, wherein an insert consists of the nucleic acid of claim 21, support for which can be found at paragraphs 23-26 of the application as filed.

New claim 34 recites a vector comprising an insert, wherein an insert consists of the nucleic acid of claim 24, support for which can be found at paragraphs 23-26 of the application as filed.

New claim 35 recites a probe comprising an insert, wherein an insert consists of the nucleic acid of claim 21, support for which can be found at paragraphs 27-29 of the application as filed.

New claim 36 recites a probe comprising an insert, wherein an insert consists of the nucleic acid of claim 24, support for which can be found at paragraphs 27-29 of the application as filed.

New claim 37 recites a gene expression inhibition system comprising the vector of claim 33 and a means for inserting said vector into a cell, support for which can be found at paragraphs 24-26 as originally filed.

New claim 38 recites a gene expression inhibition system comprising the vector of claim 34 and a means for inserting said vector into a cell, support for which can be found at paragraphs 24-26 as originally filed.

New claim 39 recites a gene expression detection system comprising the probe of claim 35 and a gene expression detector functional to selectively detect expression of at least one gene, support for which can be found at paragraphs 28-29 of the application as originally filed.

New claim 40 recites a gene expression detection system comprising the probe of claim 36 and a gene expression detector functional to selectively detect expression of at least one gene, support for which can be found at paragraphs 28-29 of the application as originally filed.

### **c. Amendments to the Specification**

Paragraph 0146 is amended to assign SEQ ID NO: 45571 to the sequence shown in Fig. 12A in compliance with 37 C.F.R. §§ 1.821-1.825.

Paragraph 0148 is amended to assign SEQ ID NOS: 45574-45579 to the listed sequences in compliance with 37 C.F.R. §§ 1.821-1.825. Paragraph 0148 is also amended to correct typographical errors.

Paragraph 0157 is amended to assign SEQ ID NO: 45572 to the sequence shown in Fig. 13A in compliance with 37 C.F.R. § 1.821-1.825.

Paragraph 0160 is amended to assign SEQ ID NO: 45573 to the sequence shown in Fig. 14A in compliance with 37 C.F.R. § 1.821-1.825.

**d. Election/Restrictions**

Groups I-IV

At pages 3-7 of the Office Action, the Examiner requires restriction to one of the following inventions under 35 U.S.C. 121:

- I. Claims 1-8, 11, 12 and 14, drawn to a bioinformatically detectable novel gene, a vector comprising said novel gene, a probe comprising said novel gene, and a vector inserter comprising said probe and a gene expression detector.
- II. Claims 9 and 10, drawn to a method of selectively inhibiting translation of at least one gene.
- III. Claim 13, drawn to a method of selectively detecting gene expression of at least one gene.
- IV. Claims 15-20, drawn to an anti-viral substance and method of anti-viral treatment capable of neutralizing RNA encoded by a bioinformatically detectable novel gene.

Applicant elects without traverse Group I, which now is considered claims 21-40, drawn to an isolated nucleic acid, a vector comprising said nucleic acid, a probe comprising said nucleic acid, a gene expression inhibition system comprising said vector and a means for inserting said vector into a cell, and a gene expression detection system comprising said probe and a gene expression detector functional to selectively detect expression of at least one gene.

**e. Sequence Election Requirement for All Groups**

At page 7 of the Office Action, the Examiner requires restriction to a single sequence.

Applicant elects with traverse nucleic acids related to SEQ ID NO: 2194 for further prosecution.

The Examiner is permitted under 35 U.S.C. 121 to issue a restriction requirement between independent and distinct inventions. However, the Director has partially waived the requirements of 37 C.F.R. § 1.141 *et seq.* to permit a reasonable number of nucleotide sequences to be claimed in a single application. *See* Examination of Patent Applications Containing Nucleotide Sequence, 1192 O.G. 68 (November 19, 1996). It has been determined that normally **ten** sequences constitute a reasonable number for examination purposes absent an exceptional case. *See* MPEP 803.04.

The Examiner has failed to demonstrate that the claimed sequences are an exceptional case necessitating that the number of sequences to be selected be less than ten. Applicant respectfully submits that the Examiner is impermissibly disregarding the waiver of 37 C.F.R. § 1.141 *et seq.* Accordingly, Applicant respectfully requests reconsideration of the restriction requirement and the opportunity to elect up to ten sequences for further prosecution.

**f. Species Election Regarding Target Genes in Group I**

At page 7 of the Office Action, the Examiner requires election of a single disclosed species for Group I under 35 U.S.C. § 121. Applicant without traverse elects SCD which has the sequence of SEQ ID NO: 22825.

## 2. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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Dated: September 21, 2006

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